

## THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.

10/672,477

Confirmation No. 8232

**Applicant** 

Rhonda A. Mills

**September 26, 2003** 

Filed

TC/A.U.

1645

Docket

121,013

Customer No.

23397

For

Method for Simultaneous Evaluation of a Sample Containing a

Cellular Target and a Soluble Analyte

Mail Stop Amendment **Commissioner for Patents** 

P.O. Box 1450

Alexandria, VA 22313-1450

## SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to the duty of disclosure provisions of 37 CFR 1.56, Applicant hereby submits Form PTO/SB/08B and a copy of the references that should be considered by the Examiner in connection with the substantive examination process.

No item of information in this Supplemental Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application.

In the event that fees should accompany this paper, the Commissioner is hereby authorized to charge the appropriate fee to Deposit Account 03-3410.

Respectfully submitted,

whelmel & alter

Mitchell E. Alter Attorney for Applicant Registration No. 28,684

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## **CERTIFICATE OF MAILING**

I HEREBY CERTIFY that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date set forth below.

NAME Maria Rodriguez

DATE\_ October 19, 2004

PTO/SB/08B (08-03)
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Substitute for form 1449/PTO				Complete if Known		
Qubantu	18 101 101111 1445/1 10			Application Number	10/672,477	
INFO	DRMATION	DIS	CLOSURE	Filing Date	September 26, 2003	
STA	TEMENT E	BY A	PPLICANT	First Named Inventor	Rhonda A. Mills	
(Use as many sheets as necessary)				Art Unit	1645	
				Examiner Name		
Sheet	1	of	3	Attorney Docket Number	121,013	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		ALBERIO, L., et al., "Rapid Determination of Anti-Heparin/Platelet Factor 4 Antibody Titers in the Diagnosis of Heparin-Induced Thrombocytopenia", Am J Med, 114:528-536 (2003)	
		AMIRAL, J., et al., "Affinity purification of heparin-dependent antibodies to platelet factor 4 developed in heparin-induced thrombocytopenia: biological characteristics and effectson platelet activation", Br J Haematol, 109:336-341 (2000)	
		BIRHIRAY, R.E., et al., Phenotypic transformation of CD52pos to CD52neg leukemic T cells as a mechanism for resistance to CAMPATH-1H", Leukemia, 16:861-864 (2002)	
		CHILVER-STAINER, L., et al., "Titre of anti-heparin/PF4-antibodies and extent of in vivo activation of the coagulation and fibrinolytic systems", Thromb Haemost, 91:276-282 (2004)	
		CHONG, B.H., et al., "Heparin-induced thrombocytopenia", J Thromb Haemost, 1:1471-1478 (2003)	
		CLARKE, L.E., "Cutaneous B-cell lymphoma with loss of CD20 immunoreactivity after rituximab therapy", J Cutan Pathol, 30:459-462 (2003)	
,	•	DAVIS, T.A., et al., "Therapy of B-Cell Lymphoma with Anti-CD20 Antibodies Can Result in the Loss of CD20 Antigen Expression", Clin Cancer Res, 5:611-615 (1999)	
		DEBOIS, W.J., et al., "Diagnosis and treatment of heparin-induced thrombocytopenia", Perfusion, 18:47-53 (2003)	
		DUMONT, F.J., "CAMPATH (alemtuzumab) for the treatment of chronic lymphocytic leukemia and beyond", Expert Rev Anticancer Ther, 2:23-35 (2002)	
*		GILES, F.J., et al., "Circulating CD20 and CD52 in patients with non-Hodgkin's lymphoma or Hodgkin's disease", Br J Haematol, 123:850-857 (2003)	

Examiner	Date	
Signature	Considered	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Substitu	10 101 101111 1443/1 FC	,		Application Number	10/672,477		
INF	ORMATIO	N DIS	CLOSURE	Filing Date	September 26, 2003		
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		GINALDI, L, et al., "Levels of Expression of CD52 in Normal and Leukemic B and T Cells: Correlation with In vivo Therapeutic Responses to Campath-1H", Leuk Res, 22:185-191 (1997)	
		GOBBI, G., et al., "New Laboratory Test in Flow Cytometry for the Combined Analysis of Serologic and Cellular Parameters in the Diagnosis of Heparin-Induced Thrombocytopenia", Cytometry, 58B:32-38 (2004)	
		KENNEDY, G.A., et al., "Incidence and nature of CD20-negative relapses following rituximab therapy in aggressive B-cell non-Hodgkin's lymphoma: a retrospective review", Br J Haematol, 119:412-416 (2002)	
		LINDHOFF-LAST, E., et al., "Determination of heparin-platelet factor 4-lgG antiodies improves diagnosis of heparin-induced thrombocytopenia", Br J Haematol, 113:886-890 (2001)	
		MASON, D.Y., et al., "Antibody L26 recognizes an intracellular epitope on the B-cell-associated CD20 antigen", Am J Pathol, 136:1215-1222 (1990)	
		REBELLO, P., et al., "Anti-globulin Responses to Rat and Humanized Campath-1 Monoclonal Antibody Used to Treat Transplant Rejection", Transplantation, 68:1417-1420 (1999)	
		REBELLO, P., et al., "Pharmacokinetics of CAMPATH-1H: assay development and validation", J Immunol Methods, 260:285-302 (2002)	
		REILLY, R.F., "The Pathophysiology of Immune-mediated Heparin-induced thrombocytopenia", Seminars in Dialysis, 16:54-60 (2003)	
		TAYLOR, V.C., et al., "Antibody selection against CD52 produces a paroxysmal nocturnal haemoglobinuria phenotype in human lymphocytes by a novel mechanism", Biochem J, 322(Pt 3):919-925 (1997)	
		TAZZARI, P.L., "Heparin-induced thrombocytopenia: detection of antiheparin/PF4 antibodies by means of heparin/PF4-coated beads and flow cytometry", Transfus Med, 12: 193-198 (2002)	

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Signature	·	Considered	

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		NON PATENT LITERATURE DOCUMENTS	
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		UNTCH, B., et al., "Prevalence, isotype, and functionality of antiheparin-platelet factor 4 antibodies in patients treated with heparin and clinically suspected for heparin-induced thrombocytopenia, The pathogenic role of IgG", Thromb Res, 105:117-123 (2002)	
		VITALE, M., et al., "Comparison Between Different Laboratory Tests for the Detection and Prevention of Heparin-Induced Thrombocytopenia", Cytometry, 46:290-295 (2001)	
		VUN, C.M., et al., "Anti-PF4-heparin immunoglobulin G is the major class of heparin-induced thrombocytopenia antibody: findings of an enzyme-linked immunofiltration assay using membrane-bound hPF4-heparin", Br J Haematol, 112:69-75 (2001)	
		International Council for Standardization in Haematology Expert Panel on Cytometry and Int'l. Soc. of Lab. Hematol. Task Force on Platelet Counting, "Platelet Counting by the RBC/Platelet Ratio Method, A Reference Method", Am J Clin Pathol, 115:460-464 (2001)	
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